

## Senate Bill No. 1809

### CHAPTER 356

An act to amend Section 1300 of, and to add Section 1260.3 to, the Business and Professions Code, relating to healing arts, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor August 31, 2002. Filed with  
Secretary of State September 3, 2002.]

#### LEGISLATIVE COUNSEL'S DIGEST

SB 1809, Machado. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory health care personnel by the State Department of Health Services.

This bill would create a new license category for a medical laboratory technician who would be authorized to perform waived and moderate complexity tests or examinations while working under the supervision of a physician and surgeon or certain other licensed persons, and to report the test results. The bill would require the department to issue a medical laboratory technician license to each person who pays the license fee and meets specified licensure requirements. The bill would also require the department to adopt emergency regulations to implement licensure of medical laboratory technicians as soon as possible, and would authorize the department to establish licensing and renewal fees that do not exceed the costs of the department for the program.

The bill would declare that it is to take effect immediately as an urgency statute.

*The people of the State of California do enact as follows:*

SECTION 1. It is the intent of the Legislature, in enacting this act, to begin to address the critical laboratory personnel shortage in California. The Legislature further finds and declares the following:

(a) Between 70 percent and 85 percent of all physician diagnosis and treatment decisions are based upon clinical laboratory test results.

(b) California faces a shortage of over 7,000 laboratory personnel over the next 10 years.

(c) Current California training programs supply fewer than 100 new laboratory staff persons per year.

(d) There is a lack of public understanding of clinical laboratory science and a need for better educational counseling of potential laboratory personnel.

(e) The absence of qualified persons conducting clinical laboratory tests would have life or death consequences for the public.

(f) The demand for clinical laboratory services is real and growing with the aging of our population. At the same time, a majority of the qualified clinical laboratory personnel in the state are reaching retirement age.

(g) The shortage of personnel in the clinical laboratory profession necessitates the development of a career ladder to develop a supply of personnel to the clinical laboratory field.

In light of the above findings, the Legislature recognizes that creation of the medical laboratory technician category is a small but necessary step to address the severe clinical laboratory personnel shortages in California.

SEC. 2. Section 1260.3 is added to the Business and Professions Code, to read:

1260.3. (a) The department shall issue a medical laboratory technician license to each person who meets the following requirements:

(1) Has met the requirements of this chapter and any reasonable qualifications established by regulations of the department, including, but not limited to, any of the following:

(A) Lawfully holds an associate degree or an equivalent or higher degree in chemical, physical, biological, or clinical laboratory science, which includes a minimum of 36 semester units of physical or biological sciences.

(B) The completion of 60 semester (90 quarter) units from an accredited college or university, with 36 semester units in physical or biological sciences.

(C) Graduation from a medical laboratory technician training program accredited by the National Accrediting Agency for Clinical Laboratory Sciences or other recognized accrediting program approved by the department.

(D) Graduation from an advanced military medical laboratory specialist program approved by the department.

(2) Has applied for the license on forms provided by the department.

(3) Has paid a license fee established in regulations of the department in accordance with subdivision (v) of Section 1300.

(b) A licensed medical laboratory technician may perform clinical laboratory tests or examinations classified as waived or of moderate complexity under CLIA, and may report the test results. However, a licensed medical laboratory technician shall not perform microscopic

analysis or immunohematology procedures. The medical laboratory technician shall work under the supervision of a licensed physician and surgeon or a baccalaureate, masters, or doctoral level person licensed pursuant to this chapter. The supervision shall be required during the entire time a medical laboratory technician performs clinical laboratory tests or examinations.

(c) The department shall adopt emergency regulations to implement this section as soon as possible.

SEC. 3. Section 1300 of the Business and Professions Code is amended to read:

1300. The amount of application, registration, and license fees under this chapter shall be as follows:

(a) The application fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, clinical laboratory toxicologist's, clinical cytogeneticist's, or clinical molecular biologist's license is thirty-eight dollars (\$38). This fee shall be sixty-three dollars (\$63) commencing on July 1, 1983.

(b) The annual renewal fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, or clinical laboratory toxicologist's license is thirty-eight dollars (\$38). This fee shall be sixty-three dollars (\$63) commencing on July 1, 1983.

(c) The application fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is twenty-three dollars (\$23). This fee shall be thirty-eight dollars (\$38) commencing on July 1, 1983.

(d) The application and annual renewal fee for a cytotechnologist's license shall be fifty dollars (\$50) commencing on January 1, 1991.

(e) The annual renewal fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is fifteen dollars (\$15). This fee shall be twenty-five dollars (\$25) commencing on July 1, 1983.

(f) The application fee for a clinical laboratory license is six hundred dollars (\$600).

(g) The annual renewal fee for a clinical laboratory license is five hundred fifty-seven dollars (\$557).

(h) The application fee for a certificate of accreditation issued pursuant to Section 1223 is one hundred fifty dollars (\$150).

(i) The annual renewal fee for a certificate of accreditation issued pursuant to Section 1223 is one hundred dollars (\$100).

(j) In addition, clinical laboratories providing cytology services shall pay an annual fee that shall be set by the department in an amount needed to meet but not exceed the department's costs of proficiency testing and special site surveys for these laboratories, and that shall be based upon



the volume of cytologic slides examined by a laboratory. If the amount collected is less than or exceeds the amount needed for these purposes, the amount of fees collected from those laboratories in the following year shall be adjusted accordingly.

(k) The application fee for a trainee's license is eight dollars (\$8). This fee shall be thirteen dollars (\$13) commencing on July 1, 1983.

(l) The annual renewal fee for a trainee's license is five dollars (\$5). This fee shall be eight dollars (\$8) commencing on July 1, 1983.

(m) The application fee for a duplicate license is three dollars (\$3). This fee shall be five dollars (\$5) commencing on July 1, 1983.

(n) The delinquency fee is equal to the annual renewal fee.

(o) The director may establish a fee for examinations required under this chapter. The fee shall not exceed the total cost to the department in conducting the examination.

(p) The certification and renewal fees for hemodialysis technicians certified under subdivision (a) of Section 1247.6 shall be fifty dollars (\$50).

(q) The annual fee for a clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only those clinical laboratory tests or examinations considered waived under CLIA is fifty dollars (\$50). The annual fee for a clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only provider-performed microscopy, as defined under CLIA is seventy-five dollars (\$75). A clinical laboratory performing both waived and provider-performed microscopy shall pay an annual registration fee of seventy-five dollars (\$75).

(r) The costs of the department in conducting a complaint investigation, imposing sanctions, or conducting a hearing under this chapter shall be paid by the clinical laboratory. The fee shall be no greater than the fee the laboratory would pay under CLIA for the same type of activities and shall not be payable if the clinical laboratory would not be required to pay those fees under CLIA.

(s) The state, a district, city, county, city and county, or other political subdivision, or any public officer or body shall be subject to the payment of fees established pursuant to this chapter or regulations adopted thereunder.

(t) In addition to the payment of registration or licensure fees, a clinical laboratory located outside the State of California shall reimburse the department for travel and per diem to perform any necessary onsite inspections at the clinical laboratory in order to ensure compliance with this chapter.

(u) Whenever a clinical laboratory has paid registration or compliance fees, or both, to HCFA under CLIA for the same period of



time for which a license is issued under Section 1265, the fee required for the clinical laboratory license under subdivision (f) or (g), and as adjusted pursuant to Section 100450 of the Health and Safety Code, shall be reduced by the percentage of the total of all CLIA registration and compliance fees paid to HCFA by all California laboratories that are made available to the department to carry out its functions as a CLIA agent in the federal fiscal year immediately prior to when the license fee is due.

(v) The department shall establish an application fee and a renewal fee for a medical laboratory technician license, the total fees collected not to exceed the costs of the department for the implementation and operation of the program licensing and regulating medical laboratory technicians pursuant to Section 1260.3.

SEC. 4. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

The severe shortage of clinical laboratory personnel, especially personnel licensed as clinical laboratory scientists or limited clinical laboratory scientists, is creating the potential for a crisis in clinical laboratory testing capacity. A new licensure category for laboratory personnel qualified to perform waived and moderately complex testing in a clinical laboratory, the medical laboratory technician, is necessary to provide sufficient personnel capacity to deal with the current testing needs of the public. In addition, any catastrophic biological event, event of bioterrorism, or public health epidemic could not be optimally handled given the current shortage of clinical laboratory testing capacity.

In order for the residents of the state to benefit from additional qualified personnel to perform appropriate testing activities in clinical laboratories as soon as possible, and in order to provide sufficient personnel to deal with these events, it is necessary that this act take effect immediately.

